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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,836	04/25/2001	Bruce L. Roberts	GA0229	5822

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,836	ROBERTS ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 17, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed March 17, 2004 is acknowledged and entered. Claims 1-20 are pending. Claims 1-6 are under examination. Claims 7-20 remain withdrawn from consideration.

Response to Arguments

2. The rejection of claims 1-6 under 35 U.S.C. 103(a) as obvious over Diebold in view of Scheicher is withdrawn in view of Applicant's persuasive arguments. Applicant argues that the motivation for combining the teachings of Diebold and Scheicher render the resulting invention unsatisfactory for its intended purpose, and changes the principles of operation of the prior art. Specifically, Diebold teaches Ad/ManPEI/DNA complexes that are targeted to dendritic cells. The complexes are taken up into the dendritic cells by receptor-mediated endocytosis (abstract). In contrast, Scheicher teaches that a certain subset of dendritic cells are capable of taking up beads with attached antigens by phagocytosis. Applicant argues that because the two processes, endocytosis and phagocytosis, are mechanistically different, one would not have been motivated to incorporate Scheicher and Diebold.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Blaschuk *et al.* (6,358,920), herein, "Blaschuk". The claims are drawn to an adenovirus particulate comprising a plurality of adenovirus particles complexed to an insoluble micro-platform material, such as a microbead. The adenovirus particles contain a gene encoding an antigenic polypeptide. Blaschuk discloses that polynucleotides encoding a nonclassical cadherin cell adhesion recognition sequence may be incorporated into adenoviral vectors and targeted for delivery using microspheres and beads (column 68, lines 10-37). Therefore, the claims are anticipated by Blaschuk.

Claim Rejections - 35 USC § 103

4. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mountz *et al.* (WO 98/52615) in view of Blaschuk and Lisziewicz *et al.* (6,420,176), herein, "Lisziewicz". The claims are drawn to an adenovirus particulate comprising a plurality of adenovirus particles complexed to an insoluble micro-platform material. The particulate also comprises a cell binding ligand that binds a receptor, such as mannose, on a dendritic cell complexed to the insoluble material. Mountz teaches that adenovirus, expressing the Fas ligand, targets antigen presenting cells (APCs) via mannose receptors, resulting in transfection (page 23, lines 6-10 and example 34). Mountz also teaches that adenovirus is targeted to macrophages by coupling the adenovirus fiber/knob to a mannosylated polylysine peptide (page 27, lines 17-22). Mountz is

silent on the attachment of the vectors and Fas ligand to an insoluble micro-platform material, and the use of mannose as a cell binding ligand.

However, Blaschuk teaches the general principle of delivering polynucleotides via adenoviral vectors attached to beads. Lisziewics teaches that dendritic cells are targeted for adenoviral gene delivery by their receptors, such as mannose (col. 7, lines 35-62). It would have been obvious to incorporate the teachings of Blaschuk and Lisziewics into the adenovirus particle of Mountz. One would have been motivated to attach the complex of Mountz to a bead, as described by Blaschuk, in order to deliver the vector to the dendritic cell. One would have been motivated to attach mannose to the complex in order to ensure that the dendritic cells take up the complex, since dendritic cells are antigen-presenting cells. Lisziewics teaches that genetic immunization's efficiency can be enhanced with increased gene delivery to APCs (col. 6, lines 23-28). One would have had a reasonable expectation of success that adenoviral vectors and mannose attached to a bead would have targeted dendritic cells, since adenoviral vectors without beads can target dendritic cells, exemplified in Lisziewics. The addition of a bead further ensures that delivery and uptake of the complex occurs, since it is crucial for gene transfer. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

5. No claim is allowed. This action is non-final because of the new grounds of rejection. Any inconvenience is regretted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stacy B. Chen
June 9, 2004

James C. Housel 6/13/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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